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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,590	05/26/2005	Shojiro Matsuda	10873.1686USWO	9228

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EXAMINER

CHRISS, JENNIFER A

ART UNIT	PAPER NUMBER
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1794

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,590	Applicant(s) MATSUDA ET AL.	
	Examiner JENNIFER A. CHRISS	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4 - 5, 11 - 27 and 30 - 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4 - 5, 11 - 27 and 30 - 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed April 21, 2009, have been entered and have been carefully considered. Claim 1 is amended, claims 2 – 3, 6 – 10 and 28 – 29 are cancelled and claims 1, 4 – 5, 11 – 27 and 30 – 32 are pending. In view of Applicant's argument that no motivation is present to combine Browning and Harvey as they teach entirely different configurations to address entirely different needs, the Examiner withdraws all previously set forth rejections. However, upon reconsideration of Browning alone, the Examiner has applied the new set of rejections below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1, 5, 11 – 15, 25 – 26 and 30 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1).

Browning is directed to a surgical implant (Title).

As to claim 1 and 30 - 31, Browning teaches a mesh that is coated or encapsulated with an absorbable coating (page 12, lines 7 – 11). The Examiner submits that upon coating or encapsulating, the gelatin would at least a small part of the reinforcing material would be inside the gelatin film and the gelatin would be at least partially infiltrated into the reinforcing material due to the joining of the two materials.

Art Unit: 1794

Browning teaches that the absorbable material may comprise a soluble hydrogel such as gelatin (page 13, lines 6 – 8). Browning teaches that the mesh comprises bicomponent fibers comprising a nonabsorbable core and a shorter lasting absorbable surface material such as polylactic acid or polyglycolic acid (page 14, lines 28 - 31). The mesh can comprise a warp knit diamond or hexagon net (page 9, lines 11 - 14) where strand spacing is between 1 - 10 mm (page 7, lines 18 - 20), which is equated to Applicant's "vertical length" and "horizontal length". The Examiner equates the warp knit mesh to Applicant's "reinforcing material" and the gelatin coating or encapsulating material to Applicant's "gelatin film". Browning teaches the claimed invention above. It should be noted that the recitation of "antiadhesive material" is not given patentable weight at this time since the prior art meets the structural and/or chemical limitations set forth and there is nothing on record to evidence that the prior art product could not function in the desired capacity or that there is some additional implied structure associated with the term. The burden is shifted upon the Applicant to evidence the contrary.

As to claim 5, the Figures show that the surgical implant can be in sheet form.

As to claim 11, Browning teaches applying a heat treatment to the warp mesh knit to reduce fraying of the filaments (page 37, lines 1 – 6).

As to claim 12, Browning teaches that the warp knit mesh has a density of less than 50 gsm (page 8, lines 1 – 12), which significantly overlaps with Applicant's claimed range

As to claim 13, Browning teaches that the mesh comprises strands that are

Art Unit: 1794

approximately 150 - 600 microns in diameters (page 34, lines 12 - 15), therefore, the mesh will be at least 150 - 600 microns in thickness.

As to claim 15, Browning teaches that the mesh comprises bicomponent fibers comprising a nonabsorbable core and a shorter lasting absorbable surface material such as polylactic acid or polyglycolic acid (page 14, lines 28 - 31).

As to claim 25, Browning teaches that the surgical implant is capable of being absorbed by the body in a period less than 48 hours (page 15, lines 6 - 9).

As to claim 26, Browning teaches that the absorbable coating may have a thickness around 1 – 2 mm (1000 – 2000 micrometers) (page 38, lines 4 - 14).

Browning teach the claimed invention but fail to disclose that the warp knitted fabric comprises a multifilament yarn having a thickness of 30 – 200 denier. It should be noted that the linear density is a result effective variable. Browning indicates that the filaments of the mesh have a diameter of 0.02 to 0.15 mm which is directly related to denier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the knitted mesh of Browning with a yarn denier ranging from 30 to 200 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the yarn denier of Browning based on the desired strength and flexibility of the surgical implant.

Browning teach the claimed invention above but fails to teach that the yarn

Art Unit: 1794

threading tension is in a range of 0.3 - 200 N as required by claim 14 and neither rupture nor exposure of the reinforcing material occurs when the tension is less than 1 N as required by claim 32. It is reasonable to presume that the above properties are inherent to Browning. Support for said presumption is found in the use of like materials (i.e. a warp knitted mesh having diamond or hexagonal shaped pores made of a biodegradable polymer having the same unit of stitches coated with a gelatin) which would result in the claimed properties. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would obviously have been present once the Browning product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

4. Claims 17 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Matsuda (EP 1,022,031 A1).

Browning teaches the claimed invention above but fail to teach that the gelatin is cross-linked and that the gelatin is subjected to a hydrophilicity imparting treatment selected from the group consisting of a plasma treatment, glow discharge treatment, corona discharge treatment, ozone treatment, graft treatment, coating, chemical treatment, and ultraviolet treatment.

Matsuda is directed to a suturable adhesion-preventing membrane with high suture strength, good biocompatibility, decomposition and absorption in a living body (Abstract). The membrane is composed of at least one non-woven fabric layer and a coating of gelatin on the surface or surfaces of the membrane (Abstract). Matsuda notes

Art Unit: 1794

that cross-linking allows the membrane to remain in a living body while maintaining a necessary membrane strength until reconstruction of an injured surface and tissue regeneration are completed (page 6, [0043]). Matsuda teaches that the crosslinking is provided by chemical crosslinking, ultraviolet ray, thermal dehydration and other methods (page 6, [0044]). It is not seen that the specific process steps set forth in claims distinguish the presently claimed article from the prior art articles as the references expressly suggest crosslinking the gels used therein. The courts have held that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695,698,227 USPQ 964,-966 (Fed. Cir. 1985).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cross-link the gel of Browning or provide a hydrophilicity imparting treatment as suggested by Matsuda motivated by the desire to create a surgical implant which is capable of remaining in the body while maintaining the necessary strength until reconstruction of the injured surface and/or tissue regeneration are completed.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Jurgens (US 5854381).

Browning teaches the claimed invention above but fail to teach the use of 85:15 – 40:60 lactide:caprolactone copolymer.

As shown by Jurgens to was known to provide a bioabsorbable polymer comprising lactide and caprolactone in a molar ration between 90:10 and 70:30.

It would have been obvious to a person having ordinary skill in the art to have provided such a bioabsorbable material to the material of Browning in order to provide a polymer that is suitable for preventing surgical adhesions.

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Consolazio (US 4,374,063).

Browning teach the claimed invention above but fail to indicate the specific amount of endotoxin present in the gel.

Consolazio teach that the pharmaceutical field requires gels that are free from endotoxins.

It would have been obvious to a person having ordinary skill in the art to have provided an endotoxin free gel since endotoxins are bad for the body.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter: In regards to claim 4, the prior art of record fail to teach or suggest that the reinforcing material is *embedded entirely* in the gelatin film and the reinforcing material

Art Unit: 1794

and gelatin film are integrated due to gelling of gelatin that has *infiltrated entirely* in an internal part of the reinforcing material. Browning et al. teach a mesh and a coating where the coating can encapsulate the mesh or applied to at least one face of the mesh (page 12, lines 10 - 14). Browning et al. specifically note that the mesh/knit has pores in between the mesh/knit strands to further aid tissue in-growth between the members (page 10, lines 1 – 4). Although a reasonable case can be made that the coating would partially infiltrate the mesh when applying the film to the surface or encapsulating the mesh but it would not be embedded entirely or infiltrated entirely as it would interfere with the tissue ingrowth. As such, the subject matter of claim 4 is found to be allowable.

8. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Primary Examiner, Art Unit 1794

/J. A. C./
Primary Examiner, Art Unit 1794